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Appln. No. 10/053,871

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**d.) Remarks**

The specification has been amended to add the claim for priority to the provisional application, claims 1-7, 10, 12-19, 21, 23, 26, 27, 33 and 34 have been amended, and new claims 36-44 added. Please charge the requisite small entity, new claims fee of \$81 for nine (9) additional dependent claims ( $9 \times 9 = \$81$ ) to Deposit Account No. 03-1952. Thus, claims 1-44 are now pending.

**Remarks Regarding Priority**

In the Office Action, applicant is requested to add the claim for priority to the specification. The specification has been amended as requested and the claim for priority added.

**Remarks Regarding Drawings**

In the Office Action, corrected drawings as set forth in the Notice of Draftsperson's Patent Drawing Review are requested. Corrected drawings are attached hereto.

**Remarks Regarding the Specification**

In the Office Action, the examiner notes that the specification has not been checked for possible minor errors. Applicant has reviewed the specification and no corrected appear necessary.

**Remarks Regarding Claim Objection**

In the Office Action, claim 27 stands objected to as redundant of claim 26. Claim 26 has been amended to remove the redundant subject matter and this objection is moot.

**Remarks Regarding 35 U.S.C. § 112, First Paragraph**

A. Claims 1-25 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

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It is alleged that the phrase "marker" is indefinite. Applicant respectfully disagrees.

A marker (or viability marker) is clearly defined in the specification. No more is required under § 112. As disclosed in the specification, a viability marker is:

"... a microbial-enzyme substrate (viability substrate) which when incubated with the cells in the sample is taken up and may be metabolized by the actively respiring microorganism .... The viability substrate is metabolized by the microorganisms to one or more marker molecules (*see* specification, page 11, lines 27-31).

Thus, as is clear from the specification, a viability marker is a metabolized microbial enzyme substrate.

In addition, a variety of metabolized microbial enzyme substrates that are metabolized by microorganisms are disclosed in the specification. For example, some common markers are produced from tetrazolium salt which is metabolized by the microorganism to produce a water insoluble marker molecule (specification, page 16, lines 20-22). Useful tetrazolium salts include dimethylthiazolyldiphenyl, tetrazolium, iodonitrotetrazelium blue, and triphenyltetrazolium (see specification, page 16, lines 25-27, and claim 20). Other viability substrate that can be metabolized to one or more markers include markers include a nutrient of a microorganism (specification, page 16, line 31).

Thus, as is clear to one of ordinary skill in the art from reading the specification, the claimed marker is a metabolized microbial enzyme substrate. Many such markers and also substrates from which they are obtained are disclosed in the specification and the claims.

Thus, the rejection of claims 1-35, under 35 U.S.C. § 112, first paragraph, is overcome and applicant respectfully requests that it be withdrawn.

B. Claims 1-35 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

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(a) It is alleged that the specification does not enable the typing and/or enumeration of every type of microorganisms, namely parasites, virus, fungi, yeast and bacteria. Although applicant respectfully disagrees, the claims have been amended to recite that the methods and kits are directed to the typing and/or enumeration of only bacteria. Thus, this aspect of the rejection is moot.

(b) It is alleged to be unclear whether the reporter molecule is conjugated to the secondary antibody. Applicant has reviewed claim 1 and the confusion may lie in the placement of a semicolon. Accordingly, claim 1 has been amended to remove the semicolon. Claim 1 is now believed to be clear that the secondary antibody is both specific to the primary antibody and conjugated to the reporter molecule. Thus, this aspect of the rejection is moot.

(c) It is alleged that the claims do not recite the use of multiple antibodies specific for different types of microorganisms and, thus, it is unclear how one would determine what type of microorganism is present in the sample. As indicated above, applicant has limited the claims to the detection of only bacteria and, thus, this aspect of the rejection is moot.

(d) It is alleged that the phrases "rapid enumeration" and rapid detection" are unclear. Applicant respectfully disagrees. Nevertheless, solely to expedite prosecution, the term "rapid" has been deleted from the claims, and this aspect of the rejection is moot.

Thus, the rejection of claims 1-35 under 35 U.S.C. § 112, first paragraph, is overcome or moot, and applicant respectfully requests that it be withdraw.

**Remarks Regarding 35 U.S.C. § 112, Second Paragraph**

Claims 1-25 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

(a) With regard to claims 1 and 13, it is alleged that the claims do not recite the identity of a capture antibody, i.e., what the capture antibody is specific for. Although applicant

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respectfully disagrees, claims 1 and 13 have been amended to recite that the capture antibody is specific for one or more types of bacteria and this aspect of the rejection is moot.

(b) It is alleged to be unclear what happens with digested microorganisms. Although applicant respectfully disagrees, the claims have been amended to recite that digesting of the bacteria releases marker. Thus, this aspect of the rejection is moot.

(c) It is alleged that the claims are unclear in that they do not require contact between the primary antibody and the marker. Although applicant respectfully disagrees, the claims have been amended to recite that primary antibody is contacted with digested bacteria, which contains marker. Thus, this aspect of the rejection is moot.

(d) With regard to claims 12 and 23, it is alleged to be unclear what the capture antibody will capture. Although applicant respectfully disagrees, claims 1 and 13 have been amended to recite that primary antibody is specific for the one or more types of bacteria. Thus, this aspect of the rejection is moot.

(e) With regard to claim 13, it is alleged to be unclear how the primary antibody can be detected without a detectable label. Applicant respectfully disagrees and notes that the level of skill in the art of this invention is very high such that this is clear to one of ordinary skill. Further, antibody-based detection methods and kits have been commercially available for many years. It is well known to those of ordinary skill in the art that antibodies and bound antibodies can be detected with or without the detectable reporter molecules. Reporter molecules are generally preferred, but are only optional. Thus, this aspect of the rejection is overcome.

(f) With regard to claim 33, it is alleged that acronyms such as NAD should be spelled out. Appropriate corrections have been made to claim 33 and this aspect of the rejection is moot.

(g) With regard to claim 34, it is alleged that this claim does not recite a detectable label. As noted above in applicant's remarks under section (e), detectable labels are not required to detect immunological reactions. One of ordinary skill in the art is well aware of many techniques

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that detect antibody-antigen binding which do not specifically require the additional of a detectable label. Binding and/or the antibodies are detected directly. Thus, this aspect of the rejection is overcome.

(h) With regard to claims 1-24, it is alleged that these claims are incomplete for omitting essential steps. Specifically, the claims are alleged to not recite contact steps and correlation steps that correlate with the detected reporter. Although applicant respectfully disagrees, the claims have been amended, as indicated above, or already indicated exactly what binds to each antibody, what is accomplished by digestion, what is captured by a primary antibody, and what is captured by a secondary antibody. These claims are very well defined and clear to those of ordinary skill in the art. In addition, applicant has amended claims 1 and 13 to recite that the overall result, the determination of type or quantity of the one or more bacteria is determined basically from the detection of antibody bound to marker such as by detection of resulting reporter molecule. Accordingly, this aspect of the rejection is either moot or overcome.

Thus, the rejection of claims 1-25 under 35 U.S.C. § 112, second paragraph, is overcome or moot, and applicant respectfully requests that it be withdrawn.

#### **Remarks Regarding Double Patenting**

Claims 1-35 stand rejected, under the judicially created doctrine of double-patenting, as allegedly obvious over U.S. Patent No. 6,344,332. Applicant respectfully traverses this rejection. Nevertheless, enclosed herewith is a suitable Terminal Disclaimer. Thus this rejection is moot.

#### **Remarks Regarding New Claims**

New claims 36-44 have been added. These claims are all dependent claims and were added to further clarify the invention. No new matter has been added or new subject matter introduced.

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**Conclusion**

The application is in condition for examination and the prompt issuance of an Office Action is respectfully requested. If there are any fees due with the filing of this Response, including any additional fees for a further extension of time, applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 03-1952.

Respectfully submitted,  
Morrison & Foerster LLP

Date: July 11, 2003

By

  
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Enclosed: Terminal Disclaimer  
Formal Figures

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